

apparatus claims where the dilators claimed therein can exist apart from noses of users both before and after uses involving mountings of dilators on users' noses, and so can have a separate nature independently of users' noses. Figure 2 of the present specification shows a dilator in an exploded view existing independently of a user's nose since one does not appear in that figure, and that dilator is described structurally in the specification in a manner independent of being on a nose. In addition, the drawings and the specification also show dilators applied to a user's nose to thereby teach how a dilator, otherwise independent of a user's nose, can be used by the user to keep nasal passageways open. Hence, the phrases "...adapted to engage..." and "...capable of engaging..." are fully supported both as characterizing a dilator existing independently of a user's nose, and as characterizing a dilator which is used by a user on that use's nose for maintaining open the nasal passageways therein.

The Examiner further states that the quoted phrases from the claims are not supported by the specification because they include means other than the disclosed adhesive with which to engage a user's nasal outer wall tissues. However, the scope of these phrases, though broader than the single operable species disclosed, is supported by that single embodiment disclosed which is enough to provide such enablement in an arrangement involving only predictable mechanical elements. The engaging means need only have the truss member be mechanically attached to the nasal outer wall tissues so that the spring constant in the truss can operate to pull such tissues outwardly. No further disclosure is needed for support of the claims to such a predictable mechanical interface beyond this single example.

The Examiner next rejects claims 2, 6, 23 and 27 under 35 U.S.C. 112 as not being enabling for one skilled in the art to make and use the invention within the scope of these claims because the use of the phrases "...adapted to engage..." and "...capable of engaging..." in various ones of these claims is not supported by the specification due to the omitting of a critical feature in not specifying an adhesive means. The Examiner cites *In re Mayhew* for this proposition, a case in which a cooling zone element was entirely omitted from the claims at issue. Here, however, the claims rejected do in fact positively recite an "engagement means" so that there is no critical feature missing from those claims. The mere fact that a feature in claims is recited sufficiently broadly that more than one means of providing that feature is covered by those claims does not show that anything is missing

but merely allows that there be more than one way to provide that feature otherwise positively recited in those claims.

The Examiner then rejects claims 2, 3, 23, 27 and 47 under 35 U.S.C. 112 as not setting forth what the applicant regards to be in the invention. The Examiner contends evidence for this can be found in the original disclosure which is, of course, the same disclosure as is in the current application. The Examiner finds this disclosure requires that the dilator must be physically engaged with the user's nasal outer wall tissues. However, as indicated above, the specification and the drawings describe and show dilators both independent of the user's nose before use, and mounted on the user's nose during use. That is, these dilators can have separate existences independent of the user's nose as set out above.

The Examiner states that the original disclosure indicates a dilator "engaging" nasal tissues with which the applicant agrees, as indicated above, but further states that the means of engagement described therein is limited to an adhesive. However, the applicant can find no statements in the original disclosure saying that the only means of engagement can be an adhesive and, therefore, can find no limit on the means of engagement to that single embodiment. Since the Examiner admits that the original disclosure sets forth a dilator, or a truss member in a dilator, for "engaging" a user's nasal wall tissues, and points to no limitation as to the means for engagement being set forth in the specification, the applicant respectfully submits that these claims do in fact set forth the applicant's invention.

Finally, along these lines, the Examiner rejects claims 2, 6, 23, 27 and 46 under 35 U.S.C. 112 as being incomplete in omitting an essential element because of not stating the nasal dilator is positively engaged with the use's nasal outer wall tissues with an adhesive. Again, as set forth above, dilators have existences independent of the user's nose and so apparatus claims can be directed to such dilators in an unused state. These claims clearly state that the truss member has therewith an engagement means for engaging that truss member to a use's nose during use. The applicant respectfully submits that there is no gap in the relationship of the elements of the claim in these circumstances.

The Examiner then goes on to reject claims 2 through 6, 16, 21, 23, 24, 26, 36 and 47 under 35 U.S.C. 102 as being anticipated by Spanish Utility Model 289561 to Iriarte. In doing so, the Examiner contends that the body 2 of this Spanish reference serves as a flexible truss and that elastic strip 1 of that reference serves as a resilient member.

Turning first to claim 2, that claim recites a flexible strip of material having end regions adapted on one side thereof to engage the outer wall tissue of a user's nasal passages, and a resilient member positioned on the other side of that flexible strip of material. Thus, there is a flexible strip of material provided between the resilient member and the user's nose when the dilator is mounted on that nose. There is no showing of a similar arrangement in the dilators of the Spanish reference.

Rather, the Spanish reference shows the elastic strip in its disclosed dilators being between the body 2 and the user's nose during use. Such an arrangement means that the skin on a user's nose is not free to move back and forth beneath elastic strip 1 of the Spanish reference because that skin is held adhesively by body 2 substantially fixedly at the edges of this strip. This result follows because the body, in having the central part thereof firmly adhered to the top surface of the strip, cannot have the other portions thereof on the skin moved to locations beneath the strip because the edges of the strip prevent the body portion nearby from doing so due to the fixed extent of those portions. As a result, neither can the skin that is adhered to the body at the edges of the strip be brought to such positions nor can the tissues thereunder. Thus, these nasal wall skin and the nasal wall tissues immediately adjacent to the edges of elastic strip 1 are prevented from being moved under and traversing any significant distance beneath that strip during the inevitable wrinklins of the user's nose. As a result, there will be high stresses in those skin and tissue portions of the user's nose near the edges of the strip that are held nearly in place by the adhesive on body 2 during such wrinklins as the wrinkling motions attempt to force some of these portions inwardly beneath the elastic strip.

Such stresses as a source of discomfort are substantially avoided in the dilator of claim 2 of the present invention because the flexible strip of material and the skin and tissues adhered thereto are not held at the edges of the resilient bands therein. The resilient bands therein do not provide a top surface holding site for the flexible strip of material as in the Spanish reference because of being recited here as located underneath those bands. Thus, the edges of these bands located above the strip

do not become an immediate interference to portions of that strip and the tissues adhered thereto during any wrinklins of the user's nose which will tend to force those portions into moving some distance therebelow. Instead, the skin of the user's nose can move beneath the resilient band in the dilator of the present invention during such wrinklins of that nose so that undue stresses are not created in the nasal skin and wall tissues by these wrinkling movements. This is possible because the flexible strip of material can both expand in thickness and also yield in lengthwise shearing, and because the strip and the skin to which it is adhered are free to roll under the edges of the resilient bands without interference from those edges. In the absence of any showing in the Spanish reference of any intervening flexible material to separate the resilient band in a dilator from the user's nose during use so as to provide such benefits, claim 2 is clearly allowable thereover.

As to claim 3, that claim requires an adhesive void between the intermediate segment of the truss member and the bridge of the user's nose coupled with a resilient member that is located in both of the end regions which have an adhesive thereon as clarified by the above amendment. That adhesive provides for those end regions with the resilient member therein to adhesively engage the user's nose tissues. This arrangement is not shown in the Spanish reference because body 2 thereof has an adhesive edge adhered to a user's nose outside all edges of elastic strip 1 during use, including at the bridge thereof, and without there being any adhesive on that strip to adhere that strip, and so any dilator portion containing that strip, to the user's nose. Thus, there is no adhesive void in the bridge region of the user's nose because of the adherence thereto of the body edges there during use, and there is no part of the elastic strip in portions of the dilator adhered to that nose during such use. Hence, this claim is also clearly allowable over that reference.

Continuing with claim 23, that claim requires at least two resilient members being provided in the truss. The Spanish reference never shows more than a single resilient member, elastic strip 1, provided in the dilators disclosed therein, an arrangement clearly not in accord with the plural resilient member requirement of claim 23. Such a pair of resilient members allows a space to be provided therebetween in the dilator to permit transporting water vapor therethrough, and to permit two or more of the plural resilient members therein to move laterally toward one another on those occasions during which the user wrinkles his or her nose. Such a capability for allowing wrinkling

movements of a user's nose to effectively change the lateral spacing between resilient band edges greatly aids in preventing any undue stress increases in the skin and wall tissues of the user's nose adjacent to and underneath the dilator bands during such wrinklins. That is, because the plural resilient members in the dilator can move laterally toward one another, there is much less stress in the skin and adjacent tissue portions with which the dilator is engaged during a nose wrinkling since the members, at least in part, ride along with the skin motion therebelow.

In contrast, the wide single elastic strip of the Spanish reference, so wide as to nearly equal the width of the dilator, leads to large stresses occurring in that skin and tissue beneath and adjacent the edges thereof during wrinklins of the user's nose. This occurs, as pointed out above, because the body adhered over and to the elastic strip fixedly holds the skin and adjacent tissues to which it is adhered on either side of that strip at essentially those locations even during wrinklins. Hence, the use of two or more resilient bands in nasal dilators as taught by the present invention provides a substantial increase in comfort to the user over the Spanish reference dilator on those occasions when the user is wrinkling his or her nose. In these circumstances, claim 23 is clearly allowable over this reference.

Going on to claim 26, that claim depends on claim 3 and therefore should be allowable if claim 3 is allowable as has been demonstrated above. In addition, claim 26 recites providing a separating material between the truss member and the wall tissues of a user's nose to provide the adhesive void of claim 3. No such separating material is disclosed or even remotely suggested in the Spanish reference and, therefore, claim 26 should be allowable thereover.

Continuing, claim 36 requires that the surface facing the user's nose of the resilient member therein must be in contact with an adhesive that adheres that resilient member to a flexible strip of material. There is no such showing in the Spanish reference as the elastic strip of that reference is in adhesive contact with body 2 on only the surface thereof which faces away from the user's nose when that dilator is mounted thereon. Thus, claim 36 should also be allowable on this ground over the Spanish reference.

Claim 47 is required to have a resilient member and a flexible strip of material each in contact with an adhesive at a surface thereof with each such surface also facing the user's nose when

the dilator is mounted thereon. The Spanish reference shows no surface of the elastic band facing the user's nose when the dilator is mounted thereon having an adhesive thereon, so that claim 47 is clearly allowable thereover.

Claims 4 through 6 depend on claim 2, and therefore should be allowable since claim 2 is allowable as demonstrated above.

Claim 16 requires a flexible strip of material positioned between a resilient member and the outer wall tissues of a user's nose when the dilator is mounted thereon. Again, there is no showing in the Spanish reference of any material of any sort between the elastic band and the user's nose when the dilator therein is mounted on a user's nose. Claim 21 also requires having a flexible strip of deformable material positioned between the resilient member and the outer wall tissues of the user's nose when the dilator is mounted on such a nose. Thus, these claims are certainly allowable over this reference.

Finally, claim 24 depends on claim 3, and therefore should be allowable if claim 3 is allowable as has been demonstrated above.

The Examiner further continues by rejecting claims 27 through 34, 37 through 46 and 48 under 35 U.S.C. 103 as being obvious in the face of the Spanish reference.

Beginning with claim 28, the Examiner initially concedes that the required narrower intermediate section of a dilator relative to the width of the ends of that dilator set out in that claim is not shown by the Spanish reference. Nevertheless, the Examiner concludes it would be obvious to modify the shape of the Spanish reference dilator to any desired shape even though there is no shape teaching in the text of that reference and no shape suggestion other than what is shown in the figures thereof. However, narrowing the intermediate segment of a dilator is clearly a way of providing at least part of an adhesive void at the bridge of a user's nose having that dilator mounted thereon.

Beyond question, the provision of a narrowed intermediated segment reduces the amount of the dilator truss which is in contact with the user's nose at the bridge thereof to thereby increase comfort during use, while, at the same time, forms a part of an adhesive void provided to aid the user during the subsequent removal of the dilator following its use. Since the purpose of the adhesive void is to reduce the irritation to the more sensitive skin at the bridge of the nose during the

removal of a dilator, a problem not suggested or treated in any way in the Spanish reference, the narrowed intermediate segment is a significant structural improvement insofar as providing as much comfort to a user of the dilator as is possible during its removal following use while retaining the dilating force characteristic during use. Nothing in the Spanish reference in any way suggests reducing the area of the dilator at its location over the bridge of a user's nose when mounted on that nose to thereby provide comfort to the user. The applicant respectfully submits that claim 28 in these circumstances is clearly allowable over the Spanish reference.

Claim 29 depends on claim 28, and therefore should be allowable if claim 28 is allowable which has been demonstrated immediately above. In addition, claim 29 sets forth a flexible strip of material in the truss positioned to be between the resilient member and the user's nose when the dilator is mounted thereon. Again, as noted above, no such arrangement is shown in the Spanish reference where, in just the reverse order, the elastic strip is always between body and the user's nose. Similarly, claim 33, dependent on claim 32, should be allowable if claim 32 is allowable which will be demonstrated below. Claim 33 also recites a flexible strip of deformable material between the resilient member and the user's nose thereby also differing significantly from the Spanish reference. This is also true of claim 27, dependent on claim 23, which should be allowable if claim 28 is which has been demonstrated above. That is, claim 27 also recites a flexible strip of deformable material between the plural resilient members and a user's nose with the dilator mounted thereon to differ from the Spanish reference. Hence, claims 29, 33 and 27 are all allowable over the Spanish reference.

Claim 30, in depending on claim 28, should be allowable if claim 28 is allowable as has been demonstrated above. Claim 30 recites a plurality of resilient members in the truss, which, as described above, constitutes a significant improvement over the Spanish reference in providing opportunities for vapor evaporation and for the skin on the user's nose to wrinkle without substantial increases in stress therein. These problems are not disclosed anywhere in the Spanish reference, and the solution of using multiple resilient members is utterly absent from that reference. Thus, the applicant respectfully submits that claim 30 is allowable in these circumstances. Claim 34 in depending on claim 32, and claim 37 in depending on claim 36 similarly should be allowable in each reciting plural resilient members in addition to being allowable in view of the claims upon which they

depend being allowable as will be demonstrated below in the first instance, and as was demonstrated above in the second instance.

Claim 31 depends on claim 28 and claim 38 depends on claim 36, and so both should be allowable if the claims upon which they depend are allowable as has been demonstrated above. These claims also recite, as does claim 32, that the intermediate segment of the truss is not engaged with the outer wall tissues as the end surfaces are engaged to those tissues by the engagement means. This clearly differs from the Spanish reference arrangement in which any intermediate segment of the truss is at least in part engaged with the nose as are the end surfaces, because body 2 has a uniform, or nearly uniform, region outside of, and along every edge of, the elastic strip 1 so that entire peripheral region is adhered to the user's nose to thus provide nearly uniform body adherence to the nose all around strip 1. Hence, no full section of the Spanish reference dilator between the ends thereof is engaged differently with the user's nose than are those ends. In these circumstances, claims 31, 32 and 38 are clearly allowable over the Spanish reference.

Claims 39 through 46 depend on claims 2, 3, 16, 21, 23, 28, 32 and 36, respectively, and therefore should be allowable if these claims are which has been demonstrated above. Also, claim 48 depends on claim 47, and therefore should be allowable if claim 47 is allowable which has been demonstrated above. Similarly, claim 7 depends on claim 4 and claim 25 depends on claim 3, and therefore should be allowable if claims 4 and 3 are allowable as demonstrated above.

The applicant has chosen not to rewrite claim 35 in independent form at this time because claim 32 on which it depends is believed to have been demonstrated to be allowable in the foregoing. If, however, such a rewriting of claim 35 appears appropriate in the future, the applicant stands ready to do so.

The applicant does not see where the additional references cited by the Examiner, U.S. Patent 3, 742,943 to Malmin and German Patent 437,661 to Baginski, are any closer to the present invention than the references already cited and relied upon by the Examiner.

In view of the foregoing, the applicant respectfully requests the Examiner to reconsider his rejection of the claims, and further requests the Examiner now allow these claims.

The Commissioner is authorized to charge any additional fees associated with this paper

First Named Inventor: Bruce C. Johnson

Application No.: 08/874,781

-11-

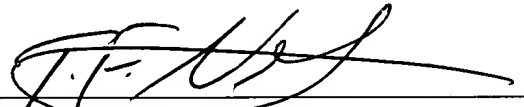
or credit any overpayment to Deposit Account No. 11-0982.

Any inquiries regarding this application should be directed to Theodore F. Neils at
(612) 339-1863.

Respectfully submitted,

KINNEY & LANGE, P.A.

By: _____



Theodore F. Neils, Reg. No. 26,316
THE KINNEY & LANGE BUILDING
312 South Third Street
Minneapolis, MN 55415-1002
Telephone: (612) 339-1863
Fax: (612) 339-6580

TFN:nab
September 22, 1999